The opinion in support of the decision being entered today is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THOMAS DAVID STARKEY

Appeal 2007-1859 Application 10/619,985 Technology Center 3700

Decided August 17, 2007

Before DONALD E. ADAMS, ERIC GRIMES, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a device and method for treating an enlarged heart. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm the rejection of all claims except claim 31.

BACKGROUND

Therapies for treating an enlarged heart "strive to make the heart smaller" (Specification 8). The Specification describes "a device used to

treat heart disease by decreasing the size of a diseased heart, or to prevent further enlargement of a diseased heart" (*id.* at 9). The device, which is a hollow sac that "simulates the shape and size of the interior lining of a normal heart," "is placed within the interior of the heart, particularly within the left ventricular cavity" (*id.*).

The Specification states that the "device works by limiting the volume of blood entering the heart during each cardiac cycle" (*id.*). "By limiting the amount of blood entering the heart, the left ventricle is not subjected to the harmful effect of excessive volume and pressure of blood during diastole, the period of the cardiac cycle when the heart is at rest" (*id.*). According to the Specification, "[t]his allows the heart to decrease in size, or to reverse remodel, and to recover lost function" (*id.*).

DISCUSSION

1. CLAIMS

Claims 1, 5, 8-11, 14-16, 18-21, and 29-31 are on appeal and are set forth in the Appendix to Appellant's Appeal Brief. Claims 32-34 are also pending but have been indicated to be allowable (Office action mailed February 3, 2005, p. 1).

The Appeal Brief states that the claims should be considered in five groups (Br. 5 and 30-31). However, the Appeal Brief does not argue the rejections in these groups, as required by 37 C.F.R. § 41.37(c)(1)(vii). For each ground of rejection, we have considered the claims in the groups in which they were argued.

Claims 1, 9, 10, 11, 14, 18, 20, 30, and 31 read as follows:

- 1. A diastolic volume limiting apparatus for insertion into a ventricle of a heart, including
 - a. a hollow plastic sac with two openings,
- b. said sac being soft and compliant so that it will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed.
- 9. A flexible sac for placement in a ventricle of a heart, said sac having a capacity for receiving a predetermined volume of blood, and said sac, when filled to capacity, appears generally in size and shape to match the size and shape of a ventricle of an undiseased human heart.
- 10. A flexible sac for insertion in a chamber of a heart, said sac having a predetermined capacity that limits the amount of blood that can be received in said sac.
- 11. The sac of claim 10 wherein said predetermined capacity is less than the capacity of the chamber of an enlarged heart.
- 14. A method of reducing stress on the wall of a chamber of a heart by inserting a flexible sac in a chamber of the heart, said sac having a predetermined maximum capacity, and connecting the sac to the annulus of the inflow valve and to the annulus of the outflow valve of the chamber.
- 18. A method of reducing stress on the walls of a chamber of a heart by limiting to a predetermined quantity the volume of blood that is allowed to enter the chamber in the diastolic phase of the heart function, and the predetermined quantity is selected so that there is minimal pressure on the walls of the chamber.

- 20. A flexible sac for insertion in a chamber of the heart, said sac limiting to a predetermined amount the volume of blood that is allowed to enter the chamber in the diastolic phase of the heart function.
- 30. A method of reducing the likelihood of enlargement of a cardiac chamber by inserting the sac of claim 20 in a chamber of the heart, as an addition to a conventional operation of the heart.
- 31. A method of treating a left ventricular aneurysm by inserting the sac of claim 20 in the left ventricle of the heart, as an addition to or step of a conventional operative repair of a left ventricular aneurysm.

2. REFERENCES

The Examiner relies on the following references:

Noon	US 4,731,076	Mar. 15, 1988
Corral	US 5,139,517	Aug. 18, 1992
Taylor	US 2002/0169360 A1	Nov. 14, 2002

3. NOON

Claims 1, 9-11, and 20 stand rejected under 35 U.S.C. § 102(b) as anticipated by Noon. The Examiner argues that Noon

teaches an apparatus fully capable of being inserted into a ventricle of a heart for limiting volume including . . . a hollow plastic sac 10 . . . with two openings 14, 16[,] . . . said sac being soft and compliant so that it will fill easily with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed.

(Answer 3.) The Examiner also argues that the "device of Noon was designed to mimic the ventricle of a human heart in size, shape, and function

... which allows it [to] fulfill the broad functional language of being 'inserted' or 'for placement' in a ventricle" (id. at 5).

We agree with the Examiner that Noon supports a prima facie case of anticipation. Noon describes "an artificial heart [and] a hydraulic bladder connected to the exterior of the artificial heart for contracting and releasing the heart in response to hydraulic pressure" (Noon, col. 1, ll. 52-57). Noon discloses that "left heart $10 \dots$ [is a] flexible bladder[] of a size and shape similar to natural hearts for implantation into a body" (*id.* at col. 2, ll. 58-64). In addition, as pointed out by the Examiner (Answer 6), both the Specification and Noon describe making their flexible sacs from segmented polyurethane (Specification 13; Noon, col. 2, ll. 64-67).

Appellant argues that Noon does not describe "a bladder to be implanted within a natural human heart. The purpose of the invention described in Noon is to drive either an artificial heart or a natural heart. Nowhere does Noon indicate that it will assist in the shrinking or 'reverse remodeling' of an enlarged heart." (Br. 9.)

We are not persuaded by these arguments. We agree with Appellant that Noon does not describe implanting its device within a chamber of a human heart. However, claims 1, 9-11, and 20 are all directed to products. The preambles of these claims recite that the device is for insertion or placement in a heart chamber, but a preamble that merely states an intended use is not a limitation. *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"). In

addition, claims 1, 9-11, and 20 do not require that the device "assist in the shrinking or 'reverse remodeling' of an enlarged heart" (Br. 9).

Appellant also argues that

the structural limitation with respect to the size of the sac being at a predetermined capacity is simply not suggested or anticipated by Noon. To the extent that the size of the bladders or artificial heart chambers of Noon are limited in size, that limitation is as a result of the outer bladder 22 surrounding the heart. There is no suggestion whatsoever that the structure of the bladder be such that it will have a limited capacity for receiving a predetermined volume of blood.

(Br. 10, 11. See also Br. 13-14 (same argument with respect to claim 20).) Appellant acknowledges that "any sac that is flexible has a limit on the volume of blood or other liquid that could be placed in the sac" (*id.* at 12). However, Appellant argues that this volume is not predetermined because "that volume is unbeknownst to Noon, and Noon does not contemplate establishing on a predetermined basis what that volume would be" (*id.*).

We are not persuaded by this argument. Claims 1 and 9-11 each recite a "predetermined" volume or capacity. In the context of these product claims, we do not agree that use of the term "predetermined" requires that an individual know this volume or capacity, or consciously establish the volume or capacity. The sac merely needs to have, for example, "a predetermined capacity that limits the amount of blood that can be received in said sac" (claim 10). As acknowledged by Appellant, "any sac that is flexible has a limit on the volume of blood or other liquid that could be placed in the sac" (Br. 12). We agree with the Examiner that this limit constitutes a predetermined volume or capacity. The volume or capacity is "predetermined" in that it is set by the physical properties of the sac,

regardless of whether anyone is aware of the volume or capacity the sac can hold.

With regard to claim 9, Appellant additionally argues that Noon "does not suggest that when his sac is filled to a predetermined volume, that the size and shape of the sac matches the size and shape of a ventricle of an undiseased human heart" (Br. 12). We are not persuaded by this argument. As discussed above, Noon discloses an artificial heart that is "of a size and shape similar to natural hearts" (Noon, col. 2, ll. 61-64). Figure 1 of Noon depicts a left heart "for a left ventricle assist" including connections to the left atrium and the aorta (see also *id.* at col. 2, l. 67, to col. 3, l. 3). Thus, we agree with the Examiner that Noon describes a flexible sac having a size and shape of a ventricle of a natural, undiseased, human heart.

With regard to claim 11, Appellant argues that there is "no suggestion . . . that the predetermined capacity of the bladder or artificial heart of Noon be less than the capacity of the chamber of an enlarged heart" (Br. 13). We are not persuaded by this argument. As discussed above, we agree with the Examiner that Noon describes a flexible sac having a size and shape of a ventricle of a natural (i.e., normal) human heart. We agree with the Examiner that the capacity of such a sac would be less than the capacity of an enlarged ventricle.

We conclude that the Examiner has set forth a prima facie case that claims 1, 9-11, and 20 are anticipated by Noon, which Appellant has not rebutted. We therefore affirm the rejection of claims 1, 9-11, and 20 under 35 U.S.C. § 102.

4. CORRAL

Claims 1, 5, 8-11, 14-16, 18-21, 29, and 30 stand rejected under 35 U.S.C. § 102(b) as anticipated by Corral. The Examiner argues that Corral teaches an apparatus for insertion into a ventricle of a heart and [that] limits volume including . . . a hollow plastic sac 46 with two openings[,] . . . said sac being soft and compliant so that it will easily fill with blood to a certain, predetermined volume, but when the sac has reached capacity, no further filling is allowed. Said apparatus is inserted into a ventricle and the opening[s] are connected to the annulus of the inflow and outflow valves.

(Answer 3-4.) The Examiner also argues that "Corral teaches the outer casing approximates the heart's normal diastolic ventricular dimensions" and that therefore "sac 46 would have a corresponding shape and would be considered to 'appear generally in size . . . heart'" (id. at 8).

With regard to the method claims, the Examiner argues that "the preamble is given no weight [because it gives] no life to the body of the claim" (id. at 9). Alternatively, the Examiner argues that "the device of Corral removes the blood pressure from the ventricle reducing stress on the wall of the chamber. The device takes over pumping and the heart can rest. A resting heart has less stress on the chamber walls and further enlargement will not occur." (Id.)

We agree with the Examiner that Corral supports a prima facie case of anticipation. Corral describes an "intraventricular pump (IVP) which . . . is surgically placed within the heart's ventricular chamber and may be used to augment either right, left or both ventricles" (Corral, col. 2, ll. 36-41). "The IVP's outer shell 44 is preferably semirigid and proportioned to approximate the natural shape of a normal ventricular chamber either left 30, or right 16"

(*id.* at col. 5, ll. 16-18). "The interior of the IVP is lined by a flexible, multilayered plastic sheet that is attached to the outer shell **44** at the inlet/outlet port area" (*id.* at col. 5, ll. 43-46).

Corral also states that the "diastolic volume of the IVP is tailored to the ideal predicted volume for the particular patient" (*id.* at col. 5, 1l. 28-30). "In dilated hearts, . . . the IVP's external shell **44** can be sized to fit the enlarged ventricle and the diaphragmatic lining can be volumetrically adjusted to ideal diastolic dimension" (*id.* at col. 6, 1l. 12-17). Alternatively, "an ideal diastolic external shell" can be engineered to "fit to the enlarged ventricle by placing a neutral compressible material between the IVP and ventricle" (*id.* at col. 6, 1l. 19-23).

Appellant argues that "the Corral device does not include a sac that is soft and compliant and that will fill easily with blood to a predetermined volume, but when said sac is reached to capacity, no further filling is allowed" (Br. 14). Specifically, Appellant argues that, in Corral,

the outer shell 44 limits the extent to which the liner 46 can expand. The use of an external device such as the outer shell 44 to limit the ability of the sac to receive a predetermined volume of blood is substantially different from Applicant's invention in which a single element, the sac, limits the volume of blood that can be received in its chamber, and when the sac has reached it[s] capacity as established by the sac, not some outside element, no further filling is allowed.

(*Id.* See also *id.* at 16-20 (same argument with respect to claims 5, 9, 10, 14-16, 20, and 21).)

We are not persuaded by this argument. As acknowledged by Appellant, "any sac that is flexible has a limit on the volume of blood or other liquid that could be placed in the sac" (Br. 12). Thus, we agree with

the Examiner that Corral's flexible, multilayered plastic lining can be filled "to a certain, predetermined volume," and that, "when the sac has reached capacity, no further filling is allowed." Whether or not Corral's plastic lining is able to reach its capacity while in the outer shell is not relevant to whether it has a capacity over which no further filling is allowed because the claims do not require that the sac to be filled to its predetermined capacity.

Appellant also argues that his "invention is a substantial improvement over the Corral device because [it] eliminates the need for a second part and yet accomplishes its goals by using fewer parts while operating with greater efficien[c]y" (Br. 15). We are not persuaded by this argument. Claim 1 is directed to an apparatus "including" a sac. Based on this open-ended claim language, claim 1 does not exclude Corral's outer shell.

In addition, Appellant argues that his "invention is designed to allow an enlarged heart to regenerate itself and remodel to the size of a normal heart. Corral has no such purpose of his device and will not work to do that." (*Id.*) Claim 1 does not recite that its apparatus "allow[s] an enlarged heart to regenerate itself and remodel to the size of a normal heart." Therefore, we are not persuaded by this argument.

Appellant argues that claim 8 is allowable "because there is no suggestion in Corral that the liner be a size and shape so that when filled, it will appear generally in size and shape to match the size and shape of a ventricle of an undiseased human heart." (Br. 16. See also *id.* at 17 (same argument with respect to claim 9.))

We are not persuaded by these arguments. Corral states that the outer shell of its device is "proportioned to approximate the natural shape of a

normal ventricular chamber" and that the "interior of the IVP is lined by a flexible, multilayered plastic sheet" (Corral, col. 5, ll. 16-45). Therefore, we agree with the Examiner that Corral describes forming a sac "so that when the sac is filled to capacity, it will appear generally in size and shape to match the size and shape of a ventricle of an undiseased human heart," as recited in claim 8.

Appellant argues that claim 11 is allowable because Corral does not disclose that "the predetermined capacity of the sac [is] less than the capacity of the chamber of an enlarged heart" (Br. 18). In fact, Appellant argues that "the contrary is suggested by Corral," stating that, at column 6, beginning at line 12, "Corral suggests that in order to keep the sac from getting bigger, he must make the shell bigger or he must increase the amount of fluid that is pumped into the space between the outer shell and the liner" (id.).

We are not persuaded by these arguments. As discussed above, Corral describes an IVP having an outer shell that is "proportioned to approximate the natural shape of a normal ventricular chamber," which is "lined by a flexible, multilayered plastic sheet" (Corral, col. 5, ll. 16-45). In the context of a dilated heart, Corral describes removing the "excessive diastolic space between the ideal-sized IVP and the enlarged ventricle," and specifically states that "the diaphragmatic lining can be volumetrically adjusted to ideal diastolic dimension" (*id.* at col. 6, ll. 12-17). Thus, we agree with the Examiner that Corral describes a sac having a "predetermined capacity [that] is less than the capacity of the chamber of an enlarged heart."

With regard to claims 14-16, Appellant argues that "Corral does not discuss in any manner a method of reducing stress on the walls of a chamber of a heart by inserting a flexible sac in a chamber of the heart with said sac having a predetermined maximum capacity" (Br. 18-19). With regard to claims 15 and 16, Appellant additionally argues that Corral "does not suggest a maximum capacity that is of a volume that would cause the sac to exert only minimal pressure on the walls of the chamber of the heart" or that "the sac, when filled to maximum capacity, would exert less pressure on the walls [of] the chamber of the heart than would be exerted if the sac had not been used" (*id.* at 19).

We are not persuaded by these arguments. First, the methods of claims 14-16 do not exclude the outer shell of Corral's IVP from being inserted together with its flexible liner. Second, we conclude that the Examiner has set forth a prima facie case that inserting Corral's IVP into a heart chamber would reduce the stress on the walls of the chamber. As argued by the Examiner, "the device of Corral removes the blood pressure from the ventricle reducing stress on the wall of the chamber. The device takes over pumping and the heart can rest. A resting heart has less stress on the chamber walls." (Answer 9.) In addition, we agree that the Examiner has set forth a prima facie case that, at least in the embodiment where "the diaphragmatic lining [is] volumetrically adjusted to ideal diastolic dimension" to remove "excessive diastolic space between the ideal-sized IVP and the enlarged ventricle" (Corral, col. 6, ll. 12-17), the filled sac would exert only minimal pressure on the heart chamber walls. Appellant

has set forth no sufficient basis for concluding that the Examiner's reasoning is incorrect.

With respect to claims 18 and 19, Appellant argues that

the disclosure of Corral does not address any difference between the volume of blood that is allowed to enter the chamber of the heart as between the diastolic phase and the systolic phase. When the chamber of the heart is dilated, the volume of blood that is allowed to enter the outer shell of the Corral device is no different than the amount of blood that is allowed to enter the outer shell when the chamber is in the systolic phase. Furthermore, to the extent that the amount of blood that is in the chamber of the heart when using the Corral device is different [in] the diastolic and systolic phase[s], that difference is controlled by the outer shell, not by the liner.

(Br. 19-20.)

We are not persuaded by this argument. Claims 18 or 19 do not recite "any difference between the volume of blood that is allowed to enter the chamber of the heart as between the diastolic phase and the systolic phase" (Br. 20). Claims 18 and 19 each refer to a volume of blood that is allowed to enter the chamber in the diastolic phase. Neither claim requires that this amount be different than the amount that can enter the chamber in the systolic phase.

With respect to claims 29 and 30, Appellant argues that "[t]here is no suggestion whatsoever of using the sac of Claim 20 to either reduce the likelihood of heart enlargement either as a stand-alone item or as an

additional feature to conventional treatment of these maladies of the heart" (Br. 21).

We are not persuaded by this argument. Corral clearly describes inserting its IVP, which includes its inner lining, in the chamber of an enlarged heart (Corral, col. 6, ll. 12-23). Corral does not specifically state that this would reduce the likelihood of enlargement of the chamber. However, we agree with the Examiner that this effect would be inherent in the method described in Corral. As the Examiner reasons, "the device of Corral *removes the blood pressure from the ventricle reducing stress* on the wall of the chamber. The device takes over pumping and the heart can rest. A resting heart has less stress on the chamber walls and further enlargement will not occur." (Answer 9.) Appellant has not set forth a sufficient basis for concluding otherwise.

In summary, we conclude that the Examiner has set forth a prima facie case that claims 1, 5, 8-11, 14-16, 18-21, 29, and 30 are anticipated by Corral, which Appellant has not rebutted. We therefore affirm the rejection of claims 1, 5, 8-11, 14-16, 18-21, 29, and 30 under 35 U.S.C. § 102.

5. TAYLOR

Claims 9-11, 18-21, 30, and 31 stand rejected under 35 U.S.C. § 102(b) as anticipated by Taylor. In traversing this rejection, Appellant has

Appellant's argument refers to a "conventional treatment of [enlargement] of the heart." In contrast, claim 30 refers to "a conventional operation of the heart." Claim 30 does not require "using the sac of Claim 20 to . . . reduce the likelihood of heart enlargement . . . as an additional feature to conventional treatment of [enlargement] of the heart" (Br. 21 (emphasis added).)

grouped together claims 9-11 and claims 18-21 (Br. 22-24). The claims within these groups stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claims 10, 20, 30, and 31.

The Examiner argues that Taylor, specifically in Figures 12A-14C, "teaches a flexible sac 113, 139 for placement in a ventricle of a heart, said sac having a capacity for receiving a predetermined volume of blood" (Answer 4). The Examiner also argues that "the device of Taylor is similar/the same [as] applicant's non-elected volume compensation device (VCD) shown in applicant's figure 3" and that "[c]laims 18-21 and 30-31 are believed to be generic to appellant[']s DIVOLA (figure 1) and the VCD" (id. at 9).

With regard to claims 10 and 20, we agree with the Examiner that Taylor supports a prima facie case of anticipation. Taylor describes "[m]ethods and devices for passively assisting the cardiac function of the heart" (Taylor, Abstract). Specifically, Taylor describes a "device for displacing a volume of a portion of a diseased heart comprising an expandable member configured to fit into a chamber of the diseased heart and reduce the available blood volume of the chamber of the heart" (*id.* at ¶ [0023]). "The expandable member 113 may be an inflatable balloon which is installed in the heart in an uninflated condition and then inflated with saline fluid, water, or other well known inflation fluids" (*id.* at ¶ [0086]). Expansion of the member causes a "reduction in the effective blood volume of the diseased heart" (*id.*).

With regard to claim 10, Appellant argues that "the Taylor sac is not filled with blood" (Br. 22). However, claim 10 merely recites that the sac

has "a predetermined capacity that limits the amount of blood that can be received in said sac." There is nothing in this product claim that requires that blood be inserted into the sac.

Appellant also argues that "nothing in the Taylor reference discloses a sac with a predetermined volume or capacity" (Br. 22-23). This argument has been addressed above.

Finally, Appellant argues that "Taylor does not disclose a sac that matches the size and shape of an undiseased human heart" (Br. 23), but claim 10 does not require that the sac match the size and shape of an undiseased human heart.

We conclude that the Examiner has set forth a prima facie case that claim 10 is anticipated by Taylor, which Appellant has not rebutted. We therefore affirm the rejection of claim 10 under 35 U.S.C. § 102. Claims 9 and 11 fall with claim 10.

With regard to claim 20, Appellant argues that Taylor's sac reduces the amount of volume of blood that is allowed to enter the chamber of the heart, but it does not limit it to a predetermined volume because the walls of the heart could expand under pressure and therefore cause the heart chamber to continue to receive more and more blood as the heart enlarges. Furthermore, the device of Taylor does not minimize the pressure on the walls of the heart chamber; rather, it is more likely the device of Taylor would increase the pressure on the walls of the heart chamber.

(Br. 24.)

We are not persuaded by these arguments. First, we agree with the Examiner that Taylor's sac limits "to a predetermined amount the volume of blood that is allowed to enter the chamber in the diastolic phase of the heart

function," as recited in claim 20. As pointed out by Appellant, it is possible that the heart could enlarge increasing the predetermined amount for the next diastolic phase. However, by taking up space in the heart chamber, for any given diastolic phase, Taylor's sac limits "to a predetermined amount the volume of blood that is allowed to enter the chamber," even if that size is attained after the heart chamber has enlarged. Second, claim 20 does not require the sac to "minimize the pressure on the walls of the heart chamber."

We conclude that the Examiner has set forth a prima facie case that claim 20 is anticipated by Taylor, which Appellant has not rebutted. We therefore affirm the rejection of claim 20 under 35 U.S.C. § 102. Claims 18, 19, and 21 fall with claim 20.

With regard to claims 30 and 31, Appellant argues that

there is no suggestion whatsoever in Taylor for a method of reducing the likelihood of enlargement of a cardiac chamber by inserting a sac such as the one claimed in Claim 20 in the chamber of the heart in addition to a conventional operation of the heart; or as an additional step to the conventional operative repair of a left ventricular aneurysm.

(Br. 24.)

We reverse the § 102 rejection of claims 30 and 31 over Taylor. In particular, we agree with Appellant that the Examiner has not adequately established that the device depicted in Taylor's Figures 12 and 13 would reduce the likelihood of cardiac chamber enlargement or be useful in the treatment of a left ventricular aneurysm. Although we agree that Taylor's device appears to be similar to Appellant's VCD, the Examiner has not set forth a prima facie case that this device alone would reduce the likelihood of cardiac chamber enlargement or be useful in the treatment of a left

Appeal 2007-1859 Application 10/619,985

ventricular aneurysm, nor has the Examiner pointed to any teaching in Taylor of using this device, together with another device or procedure that would reduce the likelihood of cardiac chamber enlargement or be useful in the treatment of a left ventricular aneurysm.

SUMMARY

We affirm the rejection of claims 1, 9-11, and 20 under 35 U.S.C. § 102 over Noon, the rejection of claims 1, 5, 8-11, 14-16, 18-21, 29, and 30 under 35 U.S.C. § 102 over Corral, and the rejection of claims 9-11 and 18-21 under 35 U.S.C. § 102 over Taylor. We reverse the rejection of claims 30 and 31 under 35 U.S.C. § 102 over Taylor. Thus, claim 31 is not currently rejected.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

lbg

WADDEY & PATTERSON, P.C. 1600 DIVISION STREET, SUITE 500 NASHVILLE TN 37203